29 JUNE 2015, 11:00 – 17:00 CET
METALS CONFERENCE CENTRE – GOLD ROOM
RUE DU DUC 100 – 1150 BRUSSELS (BELGIUM)

PGM Sameness Experts Meeting

Minutes

1 Welcome and Introduction

1.1 Reminder on Confidentiality and Competition Law

Participants were reminded on their obligation to comply with confidentiality and Competition Law provisions.

1.2 Tour de table and apologies

1.3 Approval of the agenda

The Agenda was approved (Annex 1). The slides presented during the meeting are available in Annex 2.

2 Background/ Reach requirements

The PMC secretariat reminded participants on the general rules for Substance Identification (SID) under Reach:

- For sameness the 80% rule is the most relevant requirement (mono-constituent substances can be considered the same if they contain > 80% of the same constituent; 10-80% for multiconstituent substances)
- Analytical requirements: the ECHA guidance should be followed. However, some expert judgment needs to be applied: if some spectra do not provide relevant information they don't have to be provided but a justification needs to be added in the dossier. On the other hand, additional analytical information may be required in some cases
- For mono-constituent samples 'Additives' are intentionally added to stabilize the substance and are not considered impurities

Discussion: PMC has a precedent with Perrhenic acid, which is only stable as an aqueous solution. It was concluded after discussions with ECHA that if a substance is only stable in aqueous solution, the (minimum) water content has to be reported as an 'impurity', not an 'additive', as the water was not intentionally added. See further discussion under point 4 below.

Action: PMC to circulate SID cards for all PGMs in Q3 2015

3 Hydrated vs. anhydrous forms

The group agreed with the general Reach rules that hydrated and anhydrous forms can have different chemical names and different CAS numbers but can be regarded as the same substance for the purpose of a registration.

It was agreed to follow the default approach for the PGM registrations. Exceptional cases may require deviating from this rule, but this will be specifically documented.

The secretariat also reminded participants to take care when calculating tonnages, as in the default case the hydration water does not contribute to the tonnage.

Specific discussions:

- Platinum dioxide (CAS 1314-15-4) will be registered as anhydrous form only. In accordance with the provisions above, the hydrated form (which had been declared separately) will be covered in the same dossier

- The following PGM chlorides: IrCl3, RhCl3 and RuCl3 were seen as exceptional cases that cannot be covered by the default approach. The group recommended the following approach:
    - The hydrated forms are substantially different from the anhydrous forms and should not be covered in the same dossier
    - The chemical structures are significantly different: the 'hydration water' of the 'hydrates' is not bound via hydrogen bonds to the metal ion (as in normal hydrates), whereas the anhydrous forms in fact are polymeric/oligomeric complexes.
    - Because of the different chemical structures, the substance properties are also different. For example, the anhydrous forms are insoluble in water while the hydrated forms have substantial water solubilities
    - The group confirmed that for the above reasons, only the hydrated forms are of commercial relevance and require registration
    - Only the hydrated forms will therefore be registered

Action: Registrants to notify PMC by 31st July in case of disagreement with the proposed strategy, i.e., if a) anhydrous Rh-, Ru, or Ir chlorides should require registration, and if so, b) at what quantities (> 1 tpa?)

Action: For some PGM compounds, several CAS numbers are available. PMC to document this in the ID cards and make a recommendation to the PGM WG how to proceed

4 Substances available only in solution

The group agreed with the general Reach approach that solutions are considered mixtures and the substances as such should be registered.

This approach is not possible when a substance is not stable without the solvent. In that case the solution with the minimum solvent content should be registered. As the precedent with Perrhenic acid demonstrated, in such cases the solvent should be reported as 'impurity'. Since it has not intentionally been added (is was there to begin with) according to ECHA it does not qualify as an 'additive'.

The secretariat reminded participants to take care when calculating tonnages: in the above case the solvent does contribute to the tonnage.

It was agreed to follow the default approach for the PGM registrations. Exceptional cases may require deviating from this rule, but this will be specifically documented.

The following substances are not stable as solids and will require registration as solutions:

- Tetraammineplatinum dinitrate (CAS 20634-12-2). Substance is explosive when dry
- Dihydrogen hexahydroxyplatinate (CAS 68133-90-4), compound with 2-aminoethanol (1:2) cannot be isolated from solution, since the parent substance is insoluble and only soluble and stabilized/usable in alkaline solutions
- Platinum, 1,3-diethenyl-1,1,3,3-tetramethyldisiloxane complexes / Karstedt concentrate (CAS 68478-92-2)
- Dihydrogen tetrachloropalladate (CAS 16970-55-1)
- Tetraamminepalladium (II) nitrate (CAS 13601-08-6)

The following substances had initially been reported to PMC as solutions only, but it was concluded that they can also be isolated as solids and should therefore be registered as such. In the course of the sameness discussions, sameness between solid and solution will need to be demonstrated.

- Palladium sulphate (CAS 13566-03-5) can be isolated as a solid
- Tetraamminepalladium(2+) diacetate (CAS 61495-96-3)
- Rhodium tris(2-ethylhexanoate) (CAS 20845-92-5) need to confirm if can be isolated as a solid
- Dirhodium trisulphate (CAS 10489-46-0)

- Hexakis[mu-(acetato-O:O')]-µ3-oxo-triangulo-triruthenium acetate / Ruthenium acetate (CAS 55466-76-7)
- Potassium tetraoxoruthenate (CAS 31111-21-4)

Action: Registrants to notify PMC in case of disagreement, for example if solids of the above substances cannot be isolated

5 AOB, next meetings/calls and closing remarks

Sameness
The next step will be to prove sameness a) between solids from different registrants, and b) between solids and solutions (where applicable – see discussion above).
The group confirmed that the updated PMC analytical requirements (Annex 3) should be followed. In cases where solid-solution sameness is required, only Raman spectra will be needed (no infrared spectra required for the solid).
A phased approach was proposed: in a first phase, relevant spectra for Pd- and Ir-compounds will be collected. Spectra for the remaining PGMs will be collected in a second phase.

Action: Registrants to provide to PMC spectra for all Pd- and Ir-compounds as specified in Annex 3 by 30th August 2015.

PMC will then anonymise the spectra and convene a sameness meeting on 23rd September 2015 in Brussels (date tentatively confirmed by participants of this meeting).

The conclusions of the sameness discussions will be reported back to the PGM WG meeting on 14th October 2015.

Annexes
1. Agenda
2. Slides presented at the meeting
3. PMC analytical requirements

Actions

Table 1. Actions agreed at the 29 June PGM Sameness Experts Group meeting in Brussels

	What?	Who?	When?
1.	Circulate SID cards for all PGMs	PMC Sec	Q3 2015
2.	Notify PMC in case of disagreement with the proposed strategy for hydrated vs anhydrous substances, i.e., if a) anhydrous Rh-, Ru, or Ir chlorides require registration, and if so, b) at what quantities (> 1 tpa?)	Registrants	by 31st July
3.	For some PGM compounds, several CAS numbers are available. PMC to document this in the ID cards and make a recommendation to the PGM WG how to proceed	PMC Sec	After action 1
4.	Notify PMC in case of disagreement with the proposed strategy on substances available only in solution, for example if solids cannot be isolated	Registrants	by 31st July
5.	Provide to PMC spectra for all Pd- and Ir-compounds as specified in Annex 3	Registrants	30th August 2015